Retrospective non-interventional chart review study of the dosing and short-term clinical outcomes of patients with Crohn's Disease treated with ustekinumab in Finland (FINUSTE2)

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# Administrative details

| EU PAS number    |  |
|------------------|--|
| EUPAS30920       |  |
|                  |  |
| Study ID         |  |
| 43159            |  |
| DARWIN EU® study |  |
| No               |  |
| Study countries  |  |
| Finland          |  |

#### Study description

The study is an observational, retrospective, non-interventional patient chart review study, whose population is adult patients with confirmed Crohn's disease (CD) and who have initiated an intravenous ustekinumab therapy during years 2017 and 2018. The primary objective of the study is to investigate the real-life dosing patterns and the positioning of ustekinumab in the treatment of CD patients in Finland. The secondary objectives are to determine the proportion of patients continuing treatment with ustekinumab at the time of data collection, to evaluate the change in effectiveness from baseline (measured by Harvey-Bradshaw index, endoscopic score SES-CD) at 16 weeks, 1 year, 1.5 years, 2 years, and at the end of study period, and to determine the reasons for ustekinumab treatment discontinuation. This study is an extension amendment of the original FINUSTE study (EUPAS24728). In the amendment, data collection time was extended by one year (until 30.4.2019), and four new study sites were included in the study. Data collection points of 1 year, 1,5 years and 2 years were added as well, along with some minor changes. Although FINUSTE2 is not an independent study, it is registered as a separate study for clarity and transparency.

#### Study status

Finalised

### Research institutions and networks

### **Institutions**

Helsinki University Hospital (HYKS)

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A list of participating centres is provided in a separate document in section 19. Please see the attachment

### Contact details

**Study institution contact** 

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**Primary lead investigator** 

Taina Sipponen

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Actual: 20/03/2019

Study start date

Actual: 02/05/2019

#### Data analysis start date

Planned: 26/08/2019 Actual: 12/08/2019

#### **Date of final study report**

Planned: 30/09/2020 Actual: 05/04/2021

# Sources of funding

Pharmaceutical company and other private sector

### More details on funding

Janssen-Cilag AB

# Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

# Other study registration identification numbers and links

EUPAS24728 (FINUSTE)

# Methodological aspects

**.** . .

#### Study type:

Non-interventional study

#### Scope of the study:

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

#### Main study objective:

The primary objective of the study is to investigate the real-life dosing patterns and the positioning of ustekinumab in the treatment of CD patients in Finland

# Study Design

#### Non-interventional study design

Cohort

Other

### Non-interventional study design, other

Observational, non-interventional, retrospective patient chart review study

# Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**USTEKINUMAB

#### Medical condition to be studied

Crohn's disease

# Population studied

#### Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### **Estimated number of subjects**

150

# Study design details

#### **Outcomes**

The primary outcome of the study is the ustekinumab treatment and dose adjustments (mean and median ustekinumab dose and dosing interval), Secondary outcomes include disease activity measured by Harvey-Bradshaw index, and disease activity, measured by SES-CD. Both are measured at 0 and 16 weeks, 1 year, 1.5 years, 2 years, and at the end of study period.

#### **Data analysis plan**

To present the observed variables, frequencies and statistical testing for each sensible comparison. To perform statistical tests on univariate comparisons, the  $\chi^2$  test (for categorical data) and parametric tests, such as the analysis of variance (ANOVA, for continuous data) are considered if the sample size is sufficient. E.g. with less than 30 observations in a group with continuous variable being compared, non-parametric tests are considered. Where feasible, point estimates with interval estimates (confidence intervals or standard errors) are presented. P-value lower than 0.050 is considered statistically significant.

### **Documents**

#### Study, other information

190812 research centres.pdf (48.78 KB)

#### Study publications

Sipponen T, af Björkesten C-G, Hallinen T et al. A nationwide real-world study ... af Björkesten C-G, Ilus T, Hallinen T et al. Objectively assessed disease activ...

### Data management

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Data sources

### **Data sources (types)**

Other

### Data sources (types), other

Routine secondary care electronic patient registry

### Use of a Common Data Model (CDM)

### **CDM** mapping

No

# Data quality specifications

### **Check stability**

**Check conformance** 

Unknown

### **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No